K103657

510(k) Summary

AUG - 9 2011

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

Submitter:	OrbusNeich Medical, Inc. 5363 NW 35th Avenue Fort Lauderdale, FL 33309 Phone: 954.730.0711 Fax: 954.730.7601
Contact Person:	John D. Pazienza
Date Prepared	July 20, 2011
Trade Name:	Sapphire Coronary Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous (21 CFR 870.5100(a), Product Code LOX)
Predicate Devices:	Sprinter Legend RX (P790017 S096; cleared October 31, 2008) Voyager RX (P810046 S216; cleared June 18, 2004) Maverick (P860019 S160; cleared September 27, 2000) Apex (P860019 S208; cleared November 7, 2008) Fire Star (P880003 S090; cleared August 31, 2007)
Device Description:	The Sapphire coronary dilatation catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a polymer coated stainless steel hypotube. Lubricious coatings are applied to the distal section. The semi-compliant balloons, available in diameters from 1.5-4.0mm and lengths from 10-30mm, can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment with the exception of balloon diameters less than 2.0mm which incorporate a centrally positioned single marker band. The catheter is compatible with 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014 inch PTCA guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with a single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.
Intended Use:	The Sapphire coronary dilatation catheter is indicated for: • balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

Technological Characteristics:	Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.
Performance Data:	Both *in vitro* performance tests, such as dimensional verification, balloon preparation, deployment, and retraction, balloon rated burst pressure, balloon fatigue, balloon compliance, balloon inflation and deflation time, catheter bond strength, tip pull strength, flexibility and kinking, torque strength, radiopacity, coating integrity, and particulate evaluation, and also biocompatibility tests, such as cytotoxicity, sensitization, hemocompatibility (hemolysis, complement activation, *in vivo* thromboresistance, prothromboplastin time, and platelet and leukocyte counts), pyrogenicity, acute systemic toxicity, intracutaneous reactivity, and genotoxicity (bacterial mutagenicity and *in vitro* mouse lymphoma) were conducted on the Sapphire coronary dilatation catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the Sapphire coronary dilatation catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).
Conclusion:	This information supports a determination of substantial equivalence between the Sapphire coronary dilatation catheter and the predicate devices described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 26 2012

OrbusNeich Medical, Inc.
c/o Mr. John D. Pazienza
Director, Product Development
5363 NW 35th Avenue
Fort Lauderdale, FL 33309

Re: K103657
Trade Name: Sapphire Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Catheters, Transluminal Coronary Angioplasty, Percutaneous
Regulatory Class: II (two)
Product Code: LOX
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Pazienza:

This letter corrects our substantially equivalent letter of August 9, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: K103657

Device Name: Sapphire Coronary Dilatation Catheter

Indications for Use: The Sapphire Coronary Dilatation Catheter is indicated for:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
- balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103657